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CONFIRMATION NO. ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE APPLICATION NO. MMI-004 5456 12/14/2001 Jeanette McCarthy 10/017,724 **EXAMINER** 03/24/2004 30405 7590 CLOW, LORI A MILLENNIUM PHARMACEUTICALS, INC. 40 Landsdowne Street ART UNIT PAPER NUMBER CAMBRIDGE, MA 02139 1631

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.	Applicant(s)  MCCARTHY, JEANETTE	
10/017,724		
Examiner	Art Unit	
Lori A. Clow, Ph.D.	1631	

Office Action Cummary	Examiner	Airoint	
	Lori A. Clow, Ph.D.	1631	
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence ac	ldress
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	within the statutory minimum of thirty (30) days till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timel the mailing date of this c D (35 U.S.C. § 133).	ly. communication.
Status			
1) Responsive to communication(s) filed on	<b>⊸</b> •		
Zu/	action is non-final.		
3) Since this application is in condition for allowar	nce except for formal matters, pro	secution as to the	e merits is
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.	
Disposition of Claims			
4) ☐ Claim(s) 1-119 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-119 are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ according to the	vn from consideration.  election requirement.  r.  epted or b) □ objected to by the drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).	
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	ion is required if the drawing(s) is ob	jected to. See 37 C	FR 1.121(d). TO-152.
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the prio application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applicat rity documents have been receiv u (PCT Rule 17.2(a)).	ion No ed in this Nationa	l Stage

## Attachment(s)

I) 🔲	Notice of References Cited (PTO-892)
	Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) 🗍	Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
	Paper No(s)/Mail Date

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date
5) Notice of Informal Patent Application (PTO-152
6) Other:

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#### **DETAILED ACTION**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-36, drawn to a method for diagnosis in a vascular disease by determining the THBS2, ACE and FGB genetic profile, classified in class 435, subclass 6.
- II. Claims 37-45, drawn to a computer readable medium, electronic system, and network classified in class 702, subclass 19.
- III. Claims 46-49, drawn to a composition, classified in class 536, subclass 23.1.
- IV. Claims 50-52, drawn to kits containing probes and primers, classified in class 536, subclasses 24.3 and 24.33.
- V. Claims 53-63, drawn to a method for determining the identity of allelic variants, classified in class 435, subclass 6.
- VI. Claims 64-89, drawn to a method of assessing risk, classified in class 702, subclass 19 and Class 128, subclass 920.
- VII. Claims 90-119, drawn to a personal health report, classified in class 702, subclass 19 and Class 128, subclass 920.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (II and IV) and Group I, II, V, VI, and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid

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compositions of Group III and IV can also be used for antisense therapy, which is not required for any of the claimed methods.

The inventions of Group I, II, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case while the different inventions all recite limitations with regard to THBS2, ACE, and FGB, the different methods (and devices/systems for performing methods) are directed to different results (effects) and the method for each Group recite different method steps (function of operation) requiring a search separate from that of the method of any other group. In addition, steps in the method of one Group may be performed without knowledge of or reference to the steps or results of another Group method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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#### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

March 22, 2004

Lori A. Clow, Ph.D.

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SUPERVISORY PATENT EXAME TECHNOLOGY CENTER 1.20

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